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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,563	07/07/2003	Qun Dang	45198.00014.CON1	9007

7590 05/18/2004

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EXAMINER

BERCH, MARK L

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/615,563	Applicant(s) DANG ET AL.	
	Examiner Mark L. Berch	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-50 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 46 and 47 is/are allowed.
- 6) ☒ Claim(s) 45 and 48-50 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/12/03, 12/18/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45, 48-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 20, 36, 38 of U.S. Patent No. 6284748. Note that this parent is the grandparent of the instant application (and hence the same specification is involved), and that the scope of the genus itself is the same. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following:

A. Composition claim 50 is not patentably distinct from patent claim 1, which is drawn to the compounds. Compounds are embrative of the compositions, since a compound claim covers both the compound alone, or the compound mixed with another ingredient.

B. Claim 45 (and thus also claim 48) is drawn to "preventing diabetes". Diabetes can be prevented by suppressing any of the factors or processes which result in diabetes.

Among the causes of diabetes (that is, among the things that diabetes is second to) are Genetic diseases most notably glycogen storage disease, (and others, such as

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Friedreich's ataxia and myotonic dystrophy). Thus, when Patent claim 36 is performed, which treats glycogen storage disease, it prevents the diabetes which results from glycogen storage disease. Thus, claim 45 is just somewhat broader than patent claim 36. Claim 48 is included because the claim language does not exclude a person who has glycogen storage disease. Indeed, certain forms of glycogen storage disease are directly associated with insulin resistance.

C. Claim 49 recites treatment of atherosclerosis. Patent claim 38 is drawn to treatment of this. More broadly, Patent claim 20 covers any disease derived from abnormally elevated insulin levels, which of course would include Diabetes mellitus Type II, which in turn covers all but the third choice in claim 49 (which is covered only to a limited extent). Thus, the treatment branch of claim 49 is just a narrower version of patent claim 20.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 45 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The term "Diabetes" is ambiguous in claim 45. It is not a complete term. Diabetes insipidus for example is caused by the inability of the kidneys to conserve water, which is caused by a lack of ADH (central diabetes insipidus) or by failure of the kidneys to respond to ADH (nephrogenic diabetes insipidus). Diabetes mellitus is a collection of metabolic disorders.

Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A complete and proper composition claim must recite a carrier, otherwise it is just a compound claim. A carrier is thus needed for the claim.

Claim 45 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Diabetes in general cannot be prevented. What is preventable are forms of diabetes which are secondary to some other problem. For example, diabetes can be secondary to some pancreatic disease such as chronic pancreatitis, to cirrhosis, to some endocrine disease such as Cushing's syndrome, some genetic diseases such as glycogen storage disease, Friedreich's ataxia, myotonic dystrophy, and assorted conditions such as hyperinsulinemia which lead to diabetes. But other forms, such as Type I, are not preventable. There is no evidence of record that such compounds, or indeed any known compounds with this mode of action, can prevent diabetes in general, even if limited to diabetes mellitus.

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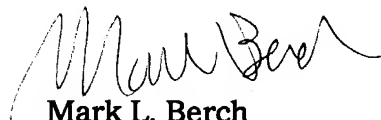
Claim 49 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim, insofar as it covers either the treatment or prevention of "ischemic injury" cannot possibly be enabled for such scope. Ischemia is an insufficient supply of blood to any organ in the body, and thus, this covers any injury which arises from this. The injury could arise from the failure of the blood to provide e.g. nutrients or oxygen, or the failure of the blood to remove waste products such as metabolites. It can arise from a blocked artery (which can come from many sources such as blood clots or artery contractions. Large numbers of causes have been assigned to such blockages, such as Smoking, High blood pressure, obesity, stress and anger, most of which have nothing at all to do with insulin. The other three items as specific disorders, but are similarly problematic. These can also arise from sources having nothing whatsoever to do with insulin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571)272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Mark L. Berch", is positioned above the printed name.

Mark L. Berch
Primary Examiner
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5/12/04